

# Amiodarone 100mg and 200mg tablets

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

## What is in this leaflet

1. **What Amiodarone tablets are and what they are used for**
2. **What you need to know before you take Amiodarone tablets**
3. **How to take Amiodarone tablets**
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### 1. **What Amiodarone tablets are and what they are used for**

Amiodarone tablets belong to a group of medicines called anti-arrhythmics. They work by regulating the heart rate.

Amiodarone tablets may be used to treat:

- severe disturbances of normal heart rhythm and irregular heart rhythm when other drugs cannot be used
- all types of irregular heartbeats of a sudden nature including a racing heart and an irregular heart rhythm when other drugs cannot be used
- Wolff-Parkinson-White Syndrome
- or restore a normal heart rhythm and maintain it.

### 2. **What you need to know before you take Amiodarone tablets**

**Do not take** Amiodarone tablets and **tell** your doctor if you:

- are **allergic** (hypersensitive) to amiodarone hydrochloride, iodine or any of the other ingredients of this medicine (see section 6)
- suffer from **conduction problems of the heart**, such as a slow heartbeat or heart block. Amiodarone tablets should only be used in such patients who have a pacemaker fitted
- have **thyroid disease** or have not yet had your thyroid function tested
- have **severely low blood pressure**
- have **severe breathing difficulties**
- are **taking the following** other medicines:
  - medicines to treat irregular heart rhythms (such as quinidine, procainamide, disopyramide) or beta blockers (such as sotalol)
  - antibiotics (erythromycin injection, co-trimoxazole, moxifloxacin)
  - pentamidine injection (used to treat pneumonia in AIDS patients)
  - medicines to treat mental illness such as chlorpromazine, thioridazine, pimozide, haloperidol, fluphenazine, amisulpride, sertindole, lithium and other antidepressants such as amitriptyline
  - medicines to treat allergic reactions (terfenadine, mizolastine)
  - medicines to treat or prevent malaria (quinine, mefloquine, chloroquine or artemether/lumefantrine)
- are **pregnant** or **breast-feeding**.

## Warnings and precautions

Talk to your doctor or pharmacist before taking Amiodarone tablets if you:

- suffer from **heart failure**
- are on a heart transplant waiting list, your doctor may change your treatment. This is because taking amiodarone before heart transplantation has shown an increased risk of a life-threatening complication (primary graft dysfunction) in which the transplanted heart stops working properly within the first 24 hours after surgery
- have **porphyria** (a genetic disease that can cause skin blisters, abdominal pain and brain or nervous system disorders)
- currently take a medicine containing sofosbuvir for the treatment of hepatitis C as it may result in a life-threatening slowing of your heartbeat. Your doctor may consider alternative treatments. If treatment with amiodarone and sofosbuvir is needed, you may require additional heart monitoring.

Tell your doctor immediately if you are taking a medicine containing sofosbuvir for the treatment of hepatitis C and during treatment you experience:

- slow or irregular heartbeat or heart rhythm problems
- shortness of breath or worsening of existing shortness of breath
- chest pain
- light-headedness
- palpitations
- near-fainting or fainting.

## Other medicines and Amiodarone tablets

**Tell your doctor or pharmacist** if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Especially:

- flecainide (to treat irregular heart rhythms)
- diltiazem or verapamil (calcium channel blockers used to treat heart conditions)
- rifampicin (antibiotic)
- stimulant laxatives (e.g. bisacodyl, senna)
- medicines that reduce blood potassium or magnesium levels such as diuretics ('water tablets'), steroids, tetracosactide or amphotericin
- anaesthetics (general or local)
- warfarin (to stop blood clotting)
- phenytoin or carbamazepine (to treat epilepsy)
- ergometrine (to treat migraines)
- digoxin (to slow fast heart rate)
- simvastatin (to lower cholesterol in the blood)
- orlistat (to reduce obesity)
- medicines to treat viral infections (e.g. atazanavir, indinavir, nelfinavir, ritonavir or saquinavir)
- midazolam (a sedative)
- fentanyl (strong pain killer)
- sildenafil (for erection problems)
- St Johns Wort (a herbal remedy)
- ciclosporin, tacrolimus or sirolimus (immune system medicines)
- sofosbuvir (for the treatment of hepatitis C).

## Pregnancy and breast-feeding

Amiodarone tablets should be avoided during pregnancy and breast-feeding. If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### **Driving and using machines**

Amiodarone tablets may cause a 'spinning' sensation or affect your vision. Make sure you are not affected before you drive or operate machinery.

### **Amiodarone tablets contain lactose**

If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicinal product.

### **Blood tests**

Whilst taking Amiodarone tablets your doctor will regularly monitor your thyroid, liver or heart function.

### **Other precautions you should take**

If you see another doctor or go into hospital, especially for an operation or if you require treatment with anaesthetics or high dose oxygen, let them know what medicines you are taking.

## **3. How to take Amiodarone tablets**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

You are advised to **moderate your alcohol intake** and **avoid grapefruit juice** with this medicine.

Swallow the tablets **with water**.

#### **Doses:**

- **Adult**

*Initially:* treatment should be started with 200mg three times a day for up to 1 week, then reduced to 200mg twice a day for a further week.

*Maintenance:* after the initial period the dose should be reduced to 200mg a day or less if appropriate.

- **Children and adolescents**

There are only limited data on the efficacy and safety in children. Your doctor will decide on an appropriate dose.

- **Elderly** take as prescribed. You may be given a lower dose.

### **If you take more Amiodarone tablets than you should**

If you (or someone else) swallow a lot of the tablets at the same time, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. If an overdose has been taken, there may be signs such as feeling or being sick, sweating, low blood pressure or changes in the heartbeat.

### **If you forget to take Amiodarone tablets**

If you forget to take a tablet take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose. Take the remaining doses at the correct time.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. Amiodarone may stay in your blood for up to a month after stopping treatment. You may still get side effects in this time.

### **Stop taking Amiodarone tablets and see a doctor or go to a hospital straight away if:**

- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swollen eyelids, face, lips, throat or tongue
- You have blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like

- symptoms and fever. This could be a condition called Stevens-Johnson syndrome
- You have a severe blistering rash in which layers of the skin may peel off to leave large areas of raw exposed skin over the body. You may also feel generally unwell, have a fever, chills and aching muscles (Toxic Epidermal Necrolysis)
  - You have inflammation of the skin characterised by fluid filled blisters (bullous dermatitis)
  - You have flu like symptoms and a rash on the face followed by an extended rash with a high temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes (DRESS)
  - Life-threatening complication after heart transplantation (primary graft dysfunction) in which the transplanted heart stops working properly (see section 2, Warnings and precautions).

**Tell your doctor if you notice any of the following side effects** or notice any other effects not listed:

**Very common** (may affect more than 1 in 10 people):

Visual disturbances (blurred vision, seeing coloured halos in dazzling light) feeling or being sick, taste disturbances particularly metallic taste, rise in some liver chemicals, sensitivity to sunlight (symptoms such as tingling, burning or redness of the skin can be minimised by limiting exposure to UV light, wearing suitable protective hats and clothing and by using a high factor sun screen).

**Common** (may affect up to 1 in 10 people):

You get yellowing of the skin or eyes (jaundice), feel tired or sick, loss of appetite, stomach pain or high temperature. These can be signs of liver problems or damage, which can be very dangerous. Shortness of breath or difficulty breathing (which may get progressively worse), tightness in the chest, coughing which will not go away, wheezing, weight loss and fever. This could be due to inflammation of your lungs which can be very dangerous and can happen at any time after starting treatment. Overactive thyroid (weight loss, restlessness, weakness, chest pain and changes in heart rhythm) and underactive thyroid (weight gain, reduced activity, sensitivity to the cold or slow heart rate), tremor including shakiness of the arms and legs and lack of co-ordination, nightmares, problems sleeping, slow heartbeat, a slate grey or bluish discolouration of light exposed skin, particularly on the face, constipation, itchy, red rash (eczema), decrease in sex drive.

**Uncommon** (may affect up to 1 in 100 people):

Muscle disease and nerve disorders (tingling of the hands and feet, numbness or weakness), new or worsening of irregular heart rhythms sometimes leading to heart attack, heart block of various degrees, including torsade de points, dry mouth.

**Rare** (may affect less than 1 in 1,000 people):

Treatment resistant raised thyroid function (sudden and severe rapid heartbeat, sweating, anxiety, increased appetite, loss of weight).

**Very rare** (may affect up to 1 in 10,000 people):

Changes in the numbers and types of your blood cells, bone marrow granulomas (inflammation of the bone marrow), hypersensitivity reaction involving blood vessel inflammation and kidney disease, cerebellar ataxia (problems walking and speaking and uncontrolled movements of the eyes), increased blood pressure in the skull (causing painful eyes, changes in vision, a bad headache especially behind the eyes), headache, 'spinning' sensation, visual problems that may lead to blindness, slowing of the heart rate in the elderly or those with existing conduction problems, asthma, liver disease or inflammation, types of skin rashes including shedding of cells, redness during radiotherapy, hair loss, swollen testicles, impotence, syndrome of inappropriate antidiuretic hormones secretion (a syndrome of excessive levels of antidiuretic hormones [hormones that help the kidneys, and body to retain water and certain levels of electrolytes in the blood to fall such as sodium]).

**Not known** (frequency cannot be estimated from the available data):

Severe allergic reaction (anaphylactic reaction, anaphylactic shock); sudden inflammation of

the pancreas (pancreatitis (acute)); decreased appetite; unusual muscle movements, stiffness, shaking and restlessness (parkinsonism); abnormal sense of smell (parosmia); confusion (delirium); seeing, hearing or feeling things that are not there (hallucinations); severe reduction in the number of white blood cells which makes infections more likely (agranulocytosis). You may get more infections than usual. This could be caused by a decrease in the number of white blood cells (neutropenia).

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Amiodarone tablets**

Keep this medicine out of the sight and reach of children.

Do not store the tablets above 25°C and store in the original packaging.

Do not use this medicine after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What Amiodarone tablets contain**

- The active substance (the ingredient that makes the tablets work) is amiodarone hydrochloride. Each tablet contains either 100mg or 200mg of the active ingredient.
- The other ingredients are maize starch, lactose monohydrate, povidone, magnesium stearate, colloidal anhydrous silica and pregelatinised starch.

### **What Amiodarone tablets look like and contents of the pack**

Amiodarone tablets BP 100mg are white, circular, uncoated tablets impressed “C” and the identifying letters “RD” on either side of a central division line on one face, with the reverse plain.

Amiodarone tablets BP 200mg are white, circular, uncoated tablets impressed “C” and the identifying letters “RE” on either side of a central division line on one face, with the reverse plain.

Pack sizes are 28 tablets

### **Marketing Authorisation Holder and Manufacturer**

Accord, Barnstaple, EX32 8NS, UK.

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